Immucor, Inc.

Declaration of Conformity *(In accordance with EN ISO/IEC 17050-1:2010)*

European Community Council Directive 98/79/EC

Digitally signed by Talpiş Andrei
Date: 2022.10.21 14:54:13 EEST
Reason: ProSign Signature
Location: Moldova

Immucor, Inc. hereby declares that the device(s) listed in appendix A to this form comply with the UK Statutory Instrument 2002:618, of The Medical Devices Regulations 2002, transposing the In Vitro Diagnostic Medical Devices Directive 98/79/EC. The List A and List B devices are in accordance with Annex IV (Full Quality Assurance) of the IVDD. The Self-Declared devices are in accordance with Annex III (EC Declaration of Conformity) of the IVDD.

Standards and Directives used in support of conformance to the In Vitro Diagnostic Medical Devices Directive 98/79/EC:

- EN ISO 13485:2012 – Quality management systems - Medical devices - Requirements for regulatory purposes
- ISO 14969:2004 – Quality management systems - Medical devices - Guidance on the application of ISO 13485:2003
- EN ISO 14971:2012 – Medical devices - Application of risk management to medical devices
- EN 13612:2002 – Performance evaluation of in vitro diagnostic medical devices
- EN ISO 23640:2011 – *In vitro* diagnostic medical devices – Evaluation of stability of *in vitro* diagnostic reagents
- EN 13641:2002 – Elimination or reduction of risk of infection related to in vitro diagnostic reagents
- ISO 14644-1:1999 – Cleanrooms and associated controlled environments - Classification of Air Cleanliness
- EN ISO 15223-1:2012 – Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2012)
- Regulation (EC) No 1272/2008 – on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 76/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
- EN ISO 18113-1:2011 – In vitro diagnostic medical devices. Information supplied by the manufacturer (labeling). Terms, definitions and general requirements.
- EN ISO 18113-2:2011 – Information supplied by the manufacturer with in vitro diagnostic reagents for professional use
- EN ISO 18113-3:2011 – In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). In Vitro diagnostic instruments for professional use
- EN 61326-1:2006 - Electrical equipment for measurement, control and laboratory use - EMC requirements – Part 1: General Requirements
- EN 60601-1-6:2010 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN 61010-1:2010 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements (Material Analyzer and Centrifuge)
- EN 61010-2-010:2003 - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of material
- EN 61010-2-020:2006 - Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-020: Particular requirements for laboratory centrifuges.
- EN 61010-2-081:2002 – Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
- EN 61010-2-101:2002 – Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- EN 62304:2006 – Medical device software – Software life cycle processes
- Directive 2006/95/EC – Low Voltage (Safety)
- Directive 2004/108/EC – Electromagnetic Compatibility (EMC)
- Directive 2002/96/EC – Waste Electrical and Electronic Equipment

This declaration is issued under the sole responsibility of Immucor, Inc. by:

Hyorek

Howard Yorek
Senior Director, Regulatory Affairs | Transfusion Diagnostics
Immucor, Inc.

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Appendix A: In Vitro Diagnostic Devices
Declaration of Conformity
Immucor, Inc.

List A and List B devices in accordance with Annex IV (Full Quality Assurance) of the IVDD

Classification: Annex II, List A

corQC Test System
corQC EXTEND Standard
corQC EXTEND 1, 2, and 3
corQC EXTEND Complete
Weak D Cells
Referencells A_1, A_2, B and O
Referencells A_1 and B
Referencells A_2
WB corQC
Anti-K

Classification: Annex II, List B

Bovine Albumin Solution 22%
ImmuAdd
pHix
Checkcell
Checkcell (Weak)
Panoscreen I and II
Panoscreen I, II and III
Hemantigen
Panocell-10
Panocell-16
Panocell-20
Panocell-10, Ficin-Treated
Capture-R Ready-Screen (I and II)
Capture-R Ready Screen (3)
Capture-R Ready-Screen (4)
Capture-R Ready-Screen (Pooled Cells)
Capture-R Ready-ID
Capture-R Ready-ID Extend I
Capture-R Ready-ID Extend II
Capture-CMV
Capture-R Ready Indicator Red Cells
Capture-CMV Indicator Red Cells
Capture LISS
Capture-R Positive Control Serum (Weak)
Capture-R Negative Control Serum
Capture-CMV Positive Control Serum (Weak)
Capture-CMV Negative Control Serum
Anti-Jk^a
Anti-Jk^b
Gamma PeG
Gamma-clone Anti-Human Globulin, Anti-IgG, -C3d; Polyspecific (Murine Monoclonal)
Gamma-clone Anti-Human Globulin, Anti-IgG (Murine Monoclonal)

Conformity assessment for Annex IV and Annex II, List A and List B devices performed by:

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Appendix A: In Vitro Diagnostic Devices
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Self-Declared devices in accordance with Annex III (EC Declaration of Conformity) of the IVDD

Classification: Self Certify (Self-Declare), Annex III

Capture-P
Capture-P Ready-Screen
Capture-P Platelet Wash and Storage Solution
Capture-P Indicator Red Cells
Capture-P Positive Control Serum (Weak)
Capture-P Negative Control Serum
Capture-R Select
TPHA Screen Test Cells
TPHA Screen Diluent
TPHA Screen Positive Control
TPHA Screen Negative Control
Red Blood Cell (RBC) Storage Solution
W.A.R.M.
RESt
H.P.C.
Freeze-Dried Papain
Complement Control Cells
DAT Positive Control Cell
Fetal Bleed Screening Test
FMH RapidScreen
Galileo Echo® Blood Bank Analyzer
CMT Plates
Specimen Diluent
Anti-Di^a
Anti-Kp^a
Anti-Kp^b
Gamma-clone Anti-Le^a (Murine Monoclonal)
Gamma-clone Anti-Le^b (Murine Monoclonal)
Anti-S
Anti-s
Gamma EGA Kit
Gamma ELU-Kit II
Gamma Lectin System
Gamma Lewis Blood Group Substance
Gamma P1 Blood Group Substance
Gamma-Quin
GammaZyme-F